AUG 2 5 2000

K002100

510(k) SUMMARY

Medical Manager Research & Development's XIMX System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Medical Manager Research & Development, Inc.
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(904) 462-2148

Contact Person:

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Date Prepared: July 11, 2000

Name of Device

XIMX System

Common or Usual Name

XIMX System

Classification Name

Picture Archiving and Communications System (PACS) (21 C.F.R. § 892.2050)

Predicate Devices

FileX System

Intended Use

The XIMX System is intended to be used as an accessory with VIDAR System Corporations', and compatible systems, digitizing and scanning systems for storing, viewing, and retrieving X-ray images. The previously cleared FileX System has the same general intended use. Thus, with respect to the intended use, the XIMX System can be found to be substantially equivalent to the previously cleared FileX System.

Principles of Operation/ Technological Character

The XIMX System has substantially equivalent technological characteristics as the previously cleared FileX System. The FileX System is comprised of three components: (1) FileX server which manages the storage and retrieval of images on magnetic media and CD-ROM; (2) FileX scan which allows for scanning in addition to features of FileX view; and (3) FileX view which allows for viewing and printing of a retained image. Support for X-ray scanning and storage is through VIDAR's VXR-8 and VXR-12 X-ray. The FileX System allows users to acquire, index, view, and print, but *not* modify, images. The FileX System has been shown to be compatible with, and is intended to be marketed as an accessory for the VIDAR X-ray system.

Substantial Equivalence

The XIMX System is intended to be used as an accessory with VIDAR System Corporations', and compatible systems, digitizing and scanning systems for storing, viewing, and retrieving X-ray images. The XIMX System has the same intended use, principles of operation and technological characteristics as the previously cleared FileX System. Thus, the XIMX System is substantially equivalent to the previously cleared FileX System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 2000

Medical Manager Research & Development, Inc.
C/O Jeffrey K. Shapiro, Esq.
Hogan & Harston L.L.P.
Columbia Square
555 13th Street, N.W.
Washington, D.C. 20004

Re: K002100
XIMX System (PACS System)
Dated: July 11, 2000
Received: July 11, 2000
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Shapiro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K002100

Medical Manager Research & Development, Inc. XIMX System Indications for Use:

The XIMX System is intended to be used as an accessory with VIDAR System Corporations', and compatible systems, digitizing and scanning systems for storing, viewing, and retrieving X-ray images.

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002100

Prescription Use ✓ OR Over–The–Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1–2–96)